APR 1 3 2011

510(k) Summary

This summary of safety and effectiveness information is being provided in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The assigned 510(k) number is: K101201

Submitter's Information:

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Date the Summary was Prepared: November 11, 2010

Device name:

- **Common Name:**

  Endosseous Dental Implant, Root-form; Endosseous Dental Implant Abutment

- **Trade Name:**

  KAT Implant System Dental Implant 6.0mm x 6.0mm; Dental Implant 6.0mm x 8.0mm; Dental Implant 6.0mm x 10.0mm; Dental Implant 7.0mm x 6.0mm; Dental Implant 7.0mm x 8.0mm; Dental Implant 7.0mm x 10.0mm; Dental Implant 8.0mm x 6.0mm; Dental Implant 8.0mm x 8.0mm; Dental Implant 8.0mm x 10.0mm

  KAT Implant System Straight (Prepable) Abutments 4.2mm x 6.5mm, Straight (Prepable) Abutments 4.6mm x 6.5mm, Straight (Prepable) Abutments 5.0mm x 6.5mm, Straight (Prepable) Abutments 5.4mm x 6.5mm, Straight (Prepable) Abutments 6.4mm x 6.5mm

- **Classification name:**

  Endosseous Dental Implant (21 CFR 872.3640, Product code DZE)

- **Classification Panel:**

  Dental

Device classification: Class II

Indications for Use:

KAT Implant System Dental Implants are indicated for restoration of edentulous maxilla and mandible, to provide support for removable dentures, fixed bridges, or to be used as a single tooth replacement. Single or splinted implants can be immediately loaded if good primary stability and appropriate occlusal loading are achieved. The implants can be placed in extraction sites or healed alveolar ridges. Immediate loading may not be appropriate in Type IV bone due to difficulty in achieving primary stability.

KAT Implant System Straight Abutment devices are intended to be used with KAT Implant System Dental Implants to aid in prosthetic rehabilitation.

Removed transitional applications

KAT Implant System (Dental Implants and Straight Abutment) is indicated for the restoration of edentulous areas in maxilla and mandible.

The legally marketed devices to which the equivalence is claimed [807.92(a)(3)]:

Predicate device: KAT Implant System Dental Implant 5.0mm x 6.0mm; Dental Implant 5.0mm x 8.0mm; Dental Implant 5.0mm x 10.0mm
Applicant: KAT Implants, LLC
510(k) number: K083544

Predicate device: KAT Implant System Implant (Indexed) Abutment 4.2mm x 6.5mm, Implant (Indexed) Abutment 4.7mm x 6.5mm, Implant (Indexed) Abutment 5.5mm x 6.5mm, Implant (Indexed) Abutment 6.5mm x 6.5mm

Applicant: KAT Implants, LLC

510(k) number: K083544

Description of Devices:

KAT Implant System Dental Implants (with outside diameters 6.0mm, 7.0mm and 8.0mm) and KAT Implant System Straight (Prepable) Abutments (with outside diameters 4.2mm, 4.6mm, 5.0mm, 5.4mm, and 6.4mm) are root-form, endosseous dental implant and implant abutment devices intended to be distributed as part of the KAT Implant System platform. KAT Implant System currently consists of implants, abutments, and Class I accessory instrumentation cleared for marketing under Traditional 510(k) Pre-marketing Notification # K083544.

Like the predicate KAT Implant System Dental Implant with outside diameter 5.0mm, the KAT Implant System Dental Implants which are subject of this 510(k) are provided in lengths of 6.0mm, 8.0mm, and 10.0mm. External V-shaped thread is similarly utilized in these new sizes of KAT Implant System Dental Implants in order to screw the implants into the bone. Horizontal fins are also placed between the thread and the abutment receiving portion of these dental implants. The abutment receiving portion of all KAT Implant System Dental Implants consists of a 3.1mm outside diameter post with a 1.5 degree taper. All KAT Implant System Dental Implants are intended to be used with previously cleared KAT Implants System Implant Abutments, as stated in Instructions for Use.

Like the predicate KAT Implant System Implant (Indexed) Abutments with outside diameters 4.2mm, 4.7mm, 5.5mm and 6.5mm, the KAT Implant Straight (Prepable) Abutments which are subject of this 510(k) consist of outside diameters within the predicate's range of outside diameters, and are 6.5mm in length. KAT Implant System Straight (Prepable) Abutments are similarly retained by the KAT Implant System Dental Implants through the abutment-receiving post. A locking-taper connection activates the seating of the abutment to the implant with the help of a torque wrench.

Like the predicate KAT Implant System Dental Implant and Implant Abutments, KAT Implant System Dental Implants and Abutments which are subject of this 510(k) are manufactured:

a) using the same Titanium-6Aluminum-4Vanadium ELI alloy (certified to meet *ASTM F136-2(a), Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI Alloy for Surgical Implant Applications* and biocompatibility requirements of *Class II Special Control Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments*);
b) undergoes the same aluminum oxide grit-blasting (compliant with blasted surfaces requirements of *Class II Special Control Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments*) and;
c) undergoes the same surface preparation processes (alkaline ultrasonication and nitric acid passivation per *ASTM F86-04, Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants*);
d) packaged with the same size and material primary packaging (in conformance with material and process requirements of *ISO 11607:2006, Packaging for Terminally-Sterilized Medical Devices*);
e) and are sterilized using the same sterilization process and sterility assurance level with SAL = 10^{-6} (per *ISO 11137:2006, Sterilization of Healthcare Products – Radiation*)

Summary of similarities and modification between the devices which are subject of this 510(k) and predicate device is presented in the table below:

Summary of Technological Characteristics

Common Name	ENDOSSEOUS DENTAL IMPLANT, ROOTFORM		IMPLANT ABUTMENT	
Device Name	**KAT Implant System Dental Implant 5.0mm**	**KAT Implant System Dental Implants**	**KAT Implant System Implant (Indexed) Abutment 4.2mm, 4.7mm, 5.5mm, 6.5mm**	**KAT Implant System Straight (Prepable) Abutment 4.2mm, 4.6mm, 5.0mm, 5.4mm, 6.4mm**
	Predicate	***Current 510(k)***	***Predicate***	***Current 510(k)***
510(K) Reference	K083544	Current 510(k)	K083544	Current 510(k)
Device Code	DZE	DZE	NHA	NHA
Device Class	Class II	Class II	Class II	Class II
Trade Name	KAT Implant System Dental Implant 5.0mm	KAT Implant System Dental Implants 6.0mm, 7.0mm and 8.0mm	KAT Implant System Implant (Indexed) Abutment 4.2mm, 4.7mm, 5.5mm, 6.5mm	KAT Implant System Straight (Prepable) Abutment 4.2mm, 4.6mm, 5.0mm, 5.4mm, 6.4mm
Outside Diameter	5.0mm	6.0mm, 7.0mm and 8.0mm	4.2mm, 4.7mm, 5.5mm, 6.5mm	4.2mm, 4.6mm, 5.0mm, 5.4mm, 6.4mm
Length	6.0mm, 8.0mm, 10.0mm, 12.0mm, 14.0mm	6.0mm, 8.0mm and 10.0mm	6.5mm	6.5mm

Essential Design Output Specifications:

Common Name	ENDOSSEOUS DENTAL IMPLANT, ROOTFORM		IMPLANT ABUTMENT	
Device Name	**KAT Implant System Dental Implants 5.0mm**	**KAT Implant System Dental Implants 6.0mm, 7.0mm and 8.0mm**	**KAT Implant System Implant (Indexed) Abutment 4.2mm, 4.7mm, 5.5mm, 6.5mm**	**KAT Implant System Straight (Prepable) Abutment 4.2mm, 4.6mm, 5.0mm, 5.4mm, 6.4mm**
	Predicate	***Current 510(k)***	***Predicate***	***Current 510(k)***
Indications for Use	KAT Implant System is intended to restore edentulous areas of maxilla and mandible, to provide support for removable	KAT Implant System Dental Implants are indicated for restoration of edentulous maxilla and mandible, to provide support for	KAT Implant System is intended to restore edentulous areas of maxilla and mandible, to provide support for removable	KAT Implant System Straight Abutment devices are intended to be used with KAT Implant System Dental Implants to aid in

	dentures, fixed bridges, or to be used as a single tooth replacement. Single or splinted implants can be immediately loaded if good primary stability and appropriate occlusal loading are achieved. The implant can be placed in extraction sites or healed alveolar ridges. Immediate loading may not be appropriate in Type IV bone due to difficulty in achieving primary stability.	removable dentures, fixed bridges, or to be used as a single tooth replacement. Single or splinted implants can be immediately loaded if good primary stability and appropriate occlusal loading are achieved. The implants can be placed in extraction sites or healed alveolar ridges. Immediate loading may not be appropriate in Type IV bone due to difficulty in achieving primary stability.	dentures, fixed bridges, or to be used as a single tooth replacement. Single or splinted implants can be immediately loaded if good primary stability and appropriate occlusal loading are achieved. The implant can be placed in extraction sites or healed alveolar ridges. Immediate loading may not be appropriate in Type IV bone due to difficulty in achieving primary stability.	prosthetic rehabilitation.
Intended Use	Intended for use by a licensed dentists familiar with surgical and prosthetic applications that uses KAT Implant System dental implants, implant abutments and Class I accessories and instrumentation. Device is not intended for use at home and is for prescription use only.	Intended for use by a licensed dentist familiar with surgical and prosthetic applications that uses KAT Implant System dental implants, implant abutments and Class I accessories and instrumentation. Device is not intended for use at home and is for prescription use only.	Intended for use by a licensed dentist familiar with surgical and prosthetic applications that uses KAT Implant System dental implants, implant abutments and Class I accessories and instrumentation. Device is not intended for use at home and is for prescription use only.	Intended for use by a licensed dentist familiar with surgical and prosthetic applications that uses KAT Implant System dental implants, implant abutments and Class I accessories and instrumentation. Device is not intended for use at home and is for prescription use only.
Device Compatibility	KAT Implant System Implant Abutments and Class I accessories and instrumentation	KAT Implant System Implant Abutments and Class I accessories and instrumentation	KAT Implant System Dental Implants and Class I accessories and instrumentation	KAT Implant System Dental Implants and Class I accessories and instrumentation
Environmental Compatibility	No known compatibility issues with devices, chemicals, and other environmental factors	No known compatibility issues with devices, chemicals, and other environmental factors	No known compatibility issues with devices, chemicals, and other environmental factors	No known compatibility issues with devices, chemicals, and other environmental factors

	reasonably expected to be present in area of device distribution and device's intended use.	reasonably expected to be present in area of device distribution and device's intended use.	reasonably expected to be present in area of device distribution and device's intended use.	reasonably expected to be present in area of device distribution and device's intended use.
Software Component	n/a	n/a	n/a	n/a
Component with Biological Origin	n/a	n/a	n/a	n/a
Design Output Specifications (General Performance and Safety)				
Type of implant	Endosseous screw type with a continuous thread and horizontal circumferential fins.	Endosseous screw type with a continuous thread and horizontal circumferential fins.	n/a	n/a
Type of abutment	n/a	n/a	Consists of abutment and indexing key which is welded to form a single piece abutment intended to be seated to implant using applied force not less than 15N-cm using a torque wrench or by using tapping force.	Consists of a single piece abutment intended to be seated to implant using applied force not less than 25N-cm using a torque wrench or by using tapping force.
Platform size	3.1mm abutment receiving post	3.1mm abutment receiving post	3.1mm internal bore	3.1mm internal bore
Type of implant / abutment connection	1.5 ° torque-activated locking taper connection	1.5 ° torque-activated locking taper connection	1.5 ° locking-taper connection with an indexing key for either: a) a torque-wrench assisted connection; b) tapping force connection; to KAT Implant System Dental Implant.	1.5 ° locking-taper connection without an indexing key for either: a) a torque-wrench assisted connection; b) tapping force connection; to KAT Implant System Dental Implant.
Surface area of the abutment / implant	3.1mm diameter / 2.75mm length connection for all	3.1mm diameter / 2.75mm length connection for all	3.1mm diameter / 2.75mm length connection for all	3.1mm diameter / 2.75mm length connection for all

interface	implants.	implants.	implants.	implants.
Angularity of Implant Abutment	n/a	n/a	0 degrees	0 degrees
Performance of the Implant/Abutment System: Rotation/Loosening	Insertion of the abutment can be implemented using a torque wrench with force not less than 15 N-cm. Insertion of the abutment can be implemented via tapping force but better calibration of force is possible when torque wrench is utilized. Rotation / loosening of the abutments are prevented not only by frictional fit, but also by the engagement between the implant post grooves and the key's protrusions.	Insertion of the abutment can be implemented using a torque wrench with force not less than 25 N-cm*. Insertion of the abutment can be implemented via tapping force but better calibration of force is possible when torque wrench is utilized. Abutments demonstrated better resistance to rotation / loosening when compared to predicate device. *(Refer to Section 18, Performance Testing, Bench for the justification of application of 25 N-cm torque in seating abutment to implant and comparison of applied torques to rotate abutment seated on an implant)	Same results as stated for KAT Implant System Dental Implant predicate. (characterization performed as implant/abutment system).	Same results as stated for KAT Implant System Dental Implant subject of this current 510(k). (characterization performed as implant/abutment system).
Performance of the Implant/Abutment System: Fatigue	Meets guidance for Fatigue testing per *Class II Special Control Guidance Document: Root-form Endosseous Dental Implant and Endosseous Implant Abutment* as tested on 3.5mm diameter implant and	Implants have greater outside diameter than the predicate device and are designed with the same 3.1mm diameter /3.5mm length abutment-receiving post. This dimensional property correlates to	Same results as stated for KAT Implant System Dental Implant predicate. (characterization performed as implant/abutment system).	Same results as stated for KAT Implant System Dental Implant subject of this current 510(k). (characterization performed as implant/abutment system).

	connected to abutment via a 3.1mm diameter /2.75mm length abutment-receiving post.	substantial equivalence with the predicate in terms of fatigue performance, if not better.		

Summary of the non-clinical test submitted as part of this submission:

Testing performed on Implant/Abutment System as presented in *Section 18, Performance Testing – Bench* yield results indicating similar threshold in applied forces as the predicate that could affect co-axial implant/abutment rotation when used as instructed.

Conclusions Drawn:

The following devices listed in this pre-marketing notification:

a) KAT Implant System Dental Implant 6.0mm x 6.0mm, Implant 6.0mm x 8.0mm, Implant 6.0mm x 10.0mm, Implant 7.0 x 6.0, Implant 7.0mm x 8.0mm, Implant 7.0mm x 10.0mm, Implant 8.0mm x 6.0mm, Implant 8.0mm x 8.0mm, Implant 8.0mm x 10.0mm;

b) KAT Implant System Straight (Prepable) Abutments 4.2mm x 6.5mm, 4.6mm x 6.5mm, 5.0mm x 6.5mm, 5.4mm x 6.5mm, 6.4mm x 6.5mm;

are substantially equivalent to the noted predicate devices based on tabulated device specifications and properties presented in the Summary of Technological Characteristics. These proposed devices are substantially equivalent to the predicate devices because they have:

- same fundamental scientific technology and intended use as the predicate device;
- same materials, processing, packaging, sterilization and inspection methods;
- same manufacturing infrastructures (both human and physical);
- same instructions for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Vitali Bondar, DDS
Chief Executive Officer
KAT Implants, LLC
15 Rye Street, Suite 115
Portsmouth, New Hampshire 03801

APR 13 2011

Re: K101201
Trade/Device Name: KAT Implant System Dental Implant 6.0mm x 6.0mm; Dental Implant 6.0mm x 8.0mm; Dental Implant 6.0mm x 10.0mm; Dental Implant 7.0mm x 6.0mm; Dental Implant 7.0mm x 8.0mm; Dental Implant 7.0mm x 10.0mm; Dental Implant 8.0mm x 6.0mm; Dental Implant 8.0mm x 8.0mm; Dental Implant 8.0mm x 10.0mm & KAT Implant System Straight (Prepable) Abutments 4.2mm x 6.5mm, Straight (Prepable) Abutments 4.6mm x 6.5mm, Straight (Prepable) Abutments 5.0mm x 6.5mm, Straight (Prepable) Abutments 5.4mm x 6.5mm, Straight (Prepable) Abutments 6.4mm x 6.5.mm
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: January 31, 2011
Received: January 31, 2011

Dear Dr. Bondar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K101201

Device Name:

KAT Implant System Dental Implant 6.0mm x 6.0mm; Dental Implant 6.0mm x 8.0mm; Dental Implant 6.0mm x 10.0mm; Dental Implant 7.0mm x 6.0mm; Dental Implant 7.0mm x 8.0mm; Dental Implant 7.0mm x 10.0mm; Dental Implant 8.0mm x 6.0mm; Dental Implant 8.0mm x 8.0mm; Dental Implant 8.0mm x 10.0mm

KAT Implant System Straight (Prepable) Abutments 4.2mm x 6.5mm, Straight (Prepable) Abutments 4.6mm x 6.5mm, Straight (Prepable) Abutments 5.0mm x 6.5mm, Straight (Prepable) Abutments 5.4mm x 6.5mm, Straight (Prepable) Abutments 6.4mm x 6.5mm

Indications for Use:

KAT Implant System dental implants and abutments are indicated for restoration of edentulous maxilla and mandible, to provide support for removable dentures, fixed bridges, or to be used as a single tooth replacement. Single or splinted implants can be immediately loaded if good primary stability and appropriate occlusal loading are achieved. The implants can be placed in extraction sites or healed alveolar ridges. Immediate loading may not be appropriate in Type IV bone due to difficulty in achieving primary stability.

Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of __

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
nfection Control, Dental Devices

510(k) Number: K10120